

SEP 28 2009

K091998

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510(K) SUMMARY

Submitter: MAKO Surgical Corp.
Address: 2555 Davie Road, Fort Lauderdale, FL, 33317
Phone number: 954-927-2044 x 605
Fax number: 954-927-0446
Contact Person: William F. Tapia
Date Prepared: June 30, 2009
Device Trade Name: Robotic Arm Interactive Orthopedic System – Hip (RIO – Hip)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO

Substantial Equivalence Claimed To: RIO – Hip is substantially equivalent to MAKO Surgical's Tactile Guidance System – Hip (K083644), Tactile Guidance System v2.0 (K081867), Brainlab's Vectorvision Hip (K010602, K040368, K052213, K072716) and Orthosoft's Navitrack System – Total Hip Replacement (K022364).

Description: The main platform includes an optical detector, computer, dedicated instrumentation, operating software, tools and accessories, drill system, and a robotic arm. The system's architecture is designed to support two main surgical applications: knee procedures (per the predicate device K081867) and hip procedures (per RIO-Hip described in this 510(k) submission). With application specific hardware and software, it provides stereotactic guidance during minimally invasive orthopedic surgical procedures by using patient CT data to assist a surgeon with presurgical planning and interpretive/intraoperative navigation. The robotic arm, once configured for a specific application (knee or hip), can serve as surgeon's "intelligent" tool holder or tool guide by passively constraining the preparation of an anatomical site for an orthopedic implant with software-defined spatial boundaries.

Summary of Technological Characteristics Compared to Predicate Devices:

The technological characteristics of RIO-Hip compared to the predicate devices are listed below:

Technological Characteristics	RIO-Hip	Tactile Guidance System (K083644, K081867)	Brainlab Vectorvision (VV) (K010602, K040368, K052213, K072716)	Orthosoft Navitrack System – Total Hip Replacement (K022364)
Major Components	Guidance Module, robotic arm, camera stand, drill system	Guidance Module, robotic arm, camera stand, drill system	Available in several different configurations (VV-Compact, VV-Sky, VV-2)	Computer cart, camera stand
Tools/accessories	Various probes, arrays tracked by optical camera	Various probes, arrays tracked by optical camera	Various probes, arrays tracked by optical camera	Various probes, arrays tracked by optical camera
Images Use	CT	CT	CT, CT-free	CT

Performance Data:

System level verification testing was performed in the laboratory with RIO-Hip using sawbone models to evaluate setup, registration, and overall accuracy and functionality of the system in supporting acetabular reaming during THA. Further testing was performed with RIO-Hip using cadaveric material where post-operative x-rays were obtained and evaluated in order to validate the system's intended use. The results of these tests satisfied all required acceptance criteria and were found to support substantial equivalence of the RIO-Hip to the predicate devices.

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Intended Use/Indications for Use:

The Robotic Arm Interactive Orthopedic System (RIO) is intended to assist the surgeon in providing software defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

The RIO is indicated for use in surgical knee and hip procedures, in which the use of stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT based model of the anatomy. These procedures include:

- Unicondylar knee replacement and/or patellofemoral knee replacement
- Acetabular reaming during total hip arthroplasty (THA)



DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 28 2009

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

MAKO Surgical Corporation
% Mr. William F. Tapia
Director, Regulatory Affairs
2555 Davie Road
Ft. Lauderdale, Florida 33317

Re: K091998

Trade/Device Name: RIO-Hip
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: OLO
Dated: September 2, 2009
Received: September 3, 2009

Dear Mr. Tapia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

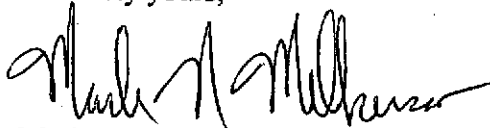
Page 2 - Mr. William F. Tapia

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091998



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EXHIBIT 1

INDICATIONS FOR USE

510(k) Number (if known): K091998

Device Name: RIO-Hip

Indications for Use:

The Robotic Arm Interactive Orthopedic System (RIO) is intended to assist the surgeon in providing software defined spatial boundaries for orientation and reference information to anatomical structures during orthopedic procedures.

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- o Unicondylar knee replacement and/or patellofemoral knee replacement
- o Acetabular reaming during total hip arthroplasty (THA)

Prescription Use X

OR

Over-the-Counter Use

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. S. [Signature]
(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091998